DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

M4029M

PURGED

July 21, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 00 - 45

Thomas DesJardins
President
Share Corporation
7821 N. Faulkner Road
Milwaukee, Wisconsin 53224

Dear Mr. DesJardins:

This letter concerns an inspection of your firm, Athea Laboratories, Inc., 7855 N. Faulkner Road, Milwaukee, Wisconsin, by the Food and Drug Administration (FDA) on February 15 and 18, 2000. During that inspection, our investigator obtained, among other things, copies of immediate container labels and formulation information for the following products manufactured and marketed by your firm:

"TOTAL SOLUTIONS MEDICATED HAND SOAP"
"[illegible] MEDICATED HAND SOAP"
"S Share Corporation MEDICATED HAND SOAP"
"[illegible]MEDICATED HAND SOAP"
"TOTAL SOLUTIONS TURBO TOWELS SANITIZING TOWELS"
"S Share Corporation PROTECTOR ANTIMICROBIAL SANITIZING TOWELS"
"[illegible] SANITIZING TOWELS"
"[illegible] SANITIZER TOWELS"

These products are offered for over-the-counter (OTC) topical antimicrobial uses through representations appearing on the labeling, such as:

"MEDICATED...BACTERIOSTATIC...sanitizes...a broad spectrum bacteriostat, works to prevent the spread of microbe born diseases that can lead to dermatitis...," "antibacterial...containing a proven broad spectrum bacteriostat.... It kills a broad spectrum of household germs...," "HAND SANITIZERS...ELIMINATES GERMS &

> BACTERIA...SANITIZES...SKIN...a powerful formula to eliminate several disease-causing germs and bacteria from the skin including...Pseudomonas aeruginosa...Staphylococcus aureus...Salmonella choleraesius...Escherichia coli...Streptococcus pyogenes.... Within seconds, this effective sanitizing formula kills 99.9% of germs and bacteria on skin...never let microbes get out of hand...," and "SANITIZING TOWELS...KILLS GERMS...."

These products are also offered for OTC skin protectant use through representations on the labeling, which include:

> "MEDICATED...protects against redness and chapping...soothe damaged skin to promote healing...," "aids in the prevention of dermatitis and chapping of hands...," and "...fortified with emollients and natural oils to prevent chapping...."

Based on these intended uses to mitigate, treat, or prevent disease, or to affect one or more of the body's structures or functions, the products named above are drugs as defined by Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

In addition, these products are "new drugs," as defined in Section 201(p) of the Act, which may not be legally marketed in this country [Section 505(a) of the Act] without an approved new drug application [Section 505(b) of the Act]. These products are in violation of these sections of the Act for one or more of the following reasons:

- We are not aware of any data showing an OTC drug product for combined antiseptic skin cleanser and skin protectant use is generally recognized as safe and effective. In the Tentative Final Monograph (TFM) for OTC first-aid antiseptics (56 FR 33644 at 33666-33667) FDA states that first-aid antiseptics combined with skin protectants are safe when used "*only*" on small surface areas of the body (e.g., minor cuts, scrapes, burns, and sunburn). Further, in the TFM for OTC health-care antiseptics FDA does not propose combining antiseptic cleansers with skin protectants, and we are not aware of such combinations having the necessary prior marketing history in the United States (U.S.) to qualify for evaluation under FDA's OTC Drug Review.

- We are not aware of data showing that an OTC antiseptic skin cleanser intended to remain on the skin without rinsing with water, as described on the labeling for the above named towel products, is generally recognized as safe and effective when labeled, among other antimicrobial uses, to "eliminate several disease-causing germs and bacteria from the skin including...Pseudomonas aeroginsa...Staphylococcus aureus...Salmonella choleraesuis...Escherichia coli...Streptcoccus pyogenes...."

- Because the labeling fails to differentiate between active and inactive ingredients, all ingredients identified thereon are represented as active ingredients for the intended "drug" uses. The labeled combination of active ingredients is not generally recognized as safe and effective by experts for the OTC topical antimicrobial or skin protectant uses as represented by statements appearing on the labeling, and it is not covered under FDA's OTC Drug Review for such uses.

  None of the labeled ingredients in "TOTAL SOLUTIONS MEDICATED HAND SOAP" are covered by the ongoing OTC Drug Review for any skin protectant use.

  Regarding " [redacted] MEDICATED HAND SOAP," the labeling identifies the ingredient "coconut oil soap" as contributing to the labeled skin protectant uses. We are not aware of data showing that this ingredient is generally recognized as safe and effective by experts and it is not covered under the OTC Drug Review for such uses.

These products are misbranded [Section 502(f)(1) of the Act] because they fail to bear adequate directions for use for the OTC topical antimicrobial and skin protectant indications listed above.

"TOTAL SOLUTIONS MEDICATED HAND SOAP," "[redacted] MEDICATED HAND SOAP," "S Share Corporation MEDICATED HAND SOAP," and "TOTAL SOLUTIONS TURBO TOWELS SANITIZING TOWELS" are further misbranded under one or both of the following sections of the Act:

- Section 502(a) - The labeling is false and misleading when it represents such product as "FDA AUTHORIZED LOT #," "FDA APPROVED," OR "FDA AUTHORIZED No. 6281926803," since there are no such authorizations or approvals.

- Section 502(b)(1) – The place of business of the manufacturer, packer, or distributor is not fully identified on the label as required by 21 CFR 210.1(I). The company name, "Total Solutions," which appears on the label for two of these products, is not listed in the current telephone directory or city directory. Thus the street address for the company must appear on the label.

Further, "TOTAL SOLUTIONS MEDICATED HAND SOAP," "[redacted] MEDICATED HAND SOAP," "S Share Corporation MEDICATED HAND SOAP," and "[redacted] MEDICATED HAND SOAP" are adulterated under Section 501(a)(4)(A) of the Act. The color additive "[redacted]" which you have identified and which your records show to be in these products, is not safe as described by Section 721(a) of the Act.

Also, your OTC drug products are adulterated under Section 501(a)(2)(B) of the Act.

The violations observed during our inspection include but are not limited to the following:

- Failure to conduct at least one test to verify the identity of each component of drug product [21 CFR 211.84(d)(1)] in that no identification test is being conducted and documented on components.

- Failure to test each component with all appropriate written specifications for purity, strength and quality [21 CFR 211.84(d)(2)] in that there are no formally written specifications for each component for comparison with Certificates of Analysis received on components.

- Failure to have written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, testing, and approval or rejection of components and drug product containers and closures [21 CFR 211.80 (a)] in that there are no written procedures describing the receipt, storage, sampling, testing, and approval or rejection of components.

- Failure to determine actual yields and percentages of theoretical yield at the conclusion of each appropriate phase of manufacturing, processing, packaging, or holding of the drug product (21 CFR 211.103) in that actual yields versus theoretical yields are not being determined or documented at appropriate phases of production.

- Failure to have written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess [21 CFR 211.100(a)] in that there is no documentation that any formal process validation has been conducted.

- Failure to have appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release, for each batch of drug product [21 CFR 211.165(a)] in that no potency/strength testing is being conducted on the finished Medicated Hand Soap & Sanitizer Towlette products.

- Failure to reject drug products that fail to meet established standards or specifications [21 CFR 211.165(f)] in that lots of finished products that failed to meet finished product specifications have been released for distribution.

- Failure to have a written testing program designed to assess the stability characteristics of drug products and failure to follow such program [21 CFR

211.166(a)] in that stability testing is not currently being conducted, and stability samples that have been collected are not held in the same container/closure system as the products being marketed.

The violations cited in this letter are not intended to be an all-inclusive statement of all the violations which may exist for products marketed by your firm. It is your responsibility to ensure adherence to each requirement of the Good Manufacturing Practice (GMP) Regulations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction. This is official notification that FDA expects all your locations to be in compliance.

Your firm has been previously informed of these GMP requirements. On June 20, 1996, a Warning Letter was sent to the president of Share Corporation, James Guenther, with copies to Peter Martin, Vice President and Director of Operations, and Steven Hipp, Technical Services Manager. The letter and the form FDA-483 issued at the conclusion of the inspection on May 16, 20-21, 1996, cited some of the same GMP deviations as are noted above.

Federal agencies are advised of the issuance of all Warning Letters about drugs so they may take this information into account when considering the award of contracts.

You should notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to Compliance Officer Carrie A. Hoffman at the address on the letterhead.

Sincerely,

Edwin S. Dee
Acting Director
Minneapolis District

CAH/ccl

Enclosure: FDA-483, 2/18/00

xc: Frank Mauro
President
Athea Laboratories, Inc.
7855 N. Faulkner Rd.
Milwaukee, WI 53224